



141-411A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATION

Re Application of:

Nicestro et al.

Serial No.: 10/761,805

Group Art Unit: --

Filed: January 21, 2004

Examiner: --

For: **NOVEL PHARMACEUTICAL FORMULATION CONTAINING A PROTON
PUMP INHIBITOR AND AN ANTACID**

New York, NY 10036
May 3, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

The following statement of relevance is submitted with the accompanying
Form PTO/SB/08A.

Document
Designation
AA
U.S.P. 4,255,431

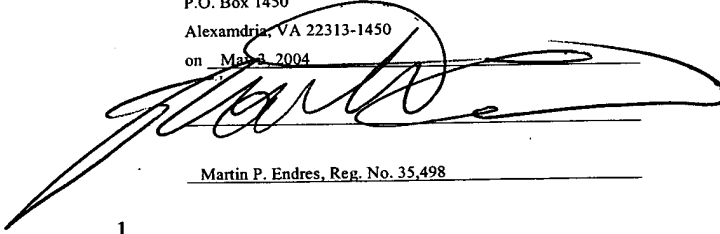
Relevance
Relates to a gastric acid secretion inhibiting substituted
2-(2-benzimidazolyl)-pyridines, pharmaceutical preparations
containing same, and method for inhibiting gastric acid
secretion.

AB
U.S.P. 4,359,465

Relates to methods for treating gastrointestinal inflammation.

I hereby certify that this correspondence is being deposited with the
United States Postal Service as first class mail in an envelope
addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
on May 3, 2004


Martin P. Endres, Reg. No. 35,498

<u>Document Designation</u>	<u>Relevance</u>
AC U.S.P. 4,686,230	Relates to a picoline derivative useful as gastric acid secretion inhibitors.
AD U.S.P. 4,786,505	Relates to pharmaceutical preparations for oral use that contain omeprazole.
AE U.S.P. 4,840,799	Relates to a process for preparing rapidly disintegrating particles.
AF U.S.P. 4,853,230	Relates to a pharmaceutical formulations of acid labile proton pump inhibitor substances for oral use.
AG U.S.P. 5,045,321	Relates to stabilized pharmaceutical compositions containing proton pump inhibitors and their production.
AH U.S.P. 5,178,867	Relates to a dosage form for delivering a drug in short time period.
AI U.S.P. 5,219,870	Relates to an omeprazole compositions designed for administration in rectum.
AJ U.S.P. 5,244,670	Relates to an ingestible pharmaceutical composition for treating upper gastrointestinal tract distress.
AK U.S.P. 5,330,982	Relates to a pharmaceutical composition containing a 5 HT receptor antagonist and a method of treating gastrointestinal disorders therewith.
AL U.S.P. 5,385,739	Relates to compositions of gastroprotected omeprazole microgranules and process for the production thereof.
AM U.S.P. 5,399,700	Relates to a method for preparing enteric coated oral drugs containing acid unstable compounds.
AN U.S.P. 5,417,980	Relates to pharmaceutical compositions and methods for treating the symptoms of overindulgence.
AO U.S.P. 5,433,959	Relates to pharmaceutical compositions containing proton pump inhibitors.
AP U.S.P. 5,508,041	Relates to microencapsulation for controlled oral drug delivery system.
AQ U.S.P. 5,693,818	Relates to a process for preparing pure salts of pyridinylmethyl-sulfinyl-1H-benzimidazole.

AR U.S.P. 5,714,504	Relates to proton pump inhibitor compositions.
AS U.S.P. 5,753,265	Relates to a multiple unit pharmaceutical preparations containing proton pump inhibitors.
AT U.S.P. 5,817,338	Relates to a multiple unit tableted dosage forms of omeprazole.
AU U.S.P. 5,840,737	Relates to omeprazole solutions and suspensions.
AV U.S.P. 5,877,192	Relates to a method for the treatment of gastric acid-related diseases and production of medication using the (-) enantiomer of omeprazole.
AW U.S.P. 6,013,281	Relates to a method of making a pharmaceutical dosage form comprising a proton pump inhibitor.
AX U.S.P. 6,027,746	Relates to a chewable soft gelatin-encapsulated pharmaceutical dosage form.
AY U.S.P. 6,096,340	Relates to an oral omeprazole dosage formulation.
AZ U.S.P. 6,132,770	Relates to a multiple unit effervescent dosage forms comprising a proton pump inhibitor.
BA U.S.P. 6,183,776	Relates to an oral pharmaceutical dosage form comprising a proton pump inhibitor and an antacid agent or alginate.
BB U.S.P. 6,248,758	Relates to a pharmaceutical dosage form comprising a proton pump inhibitor a cyclodextrin and an amino acid.
BC U.S.P. 6,296,876	Relates to a pharmaceutical formulation for an acid labile substance.
BD U.S.P. 6,365,184	Relates to an oral pharmaceutical dosage form comprising a proton pump inhibitor and an NSAID.
BE U.S.P. 6,489,346	Relates to a substituted benzimidazole dosage form and method of using same.
BF U.S. 2002/0192299	Relates to a pharmaceutical compositions of a non-enteric coated proton pump inhibitor with a carbonate salt and bicarbonate salt combination.
CA WO 85/03436	Relates to a diffusion coated multiple-unit dosage form.

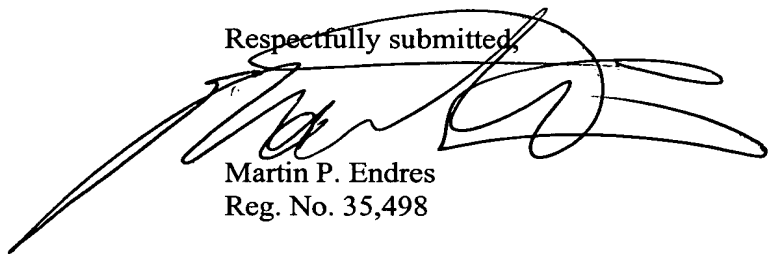
CB WO 94/02140	Relates to a pharmaceutical composition containing an antiulcer agent.
CC WO 96/01624	Relates to a multiple unit pharmaceutical preparation containing a proton pump inhibitor.
CD WO 96/37195	Relates to a pharmaceutical pellet formulation containing omeprazole.
CE WO 97/25030	Relates to a multiple unit effervescent dosage forms comprising a proton pump inhibitor.
CF WO 97/25065	Relates to an oral pharmaceutical dosage form comprising a proton pump inhibitor and a prokinetic agent.
CG WO 98/53803	Relates to a pharmaceutical formulation of omeprazole.
CH WO 00/26185	Relates to a pharmaceutical composition containing a proton pump inhibitor and a bicarbonate salt.
CI WO 01/03707	Relates to heartburn treatment using a proton pump inhibitor and an alkali metal salt of a bicarbonate.
CJ WO 02/053097	Relates to pharmaceutical compositions of a non-enteric coated proton pump inhibitor with a carbonate salt and bicarbonate salt combination.
CK EP 0 124 495	Relates to omeprazole salts and pharmaceutical formulations containing the omeprazole salts.
CL EP 0 173 664	Relates to a biologically active benzimidazole compounds process for their preparation and pharmaceutical formulations containing the compounds.
CM EP 0 338 861	Relates to antacid compositions with prolonged gastric residence time.
CN EP 0 519 144	Relates to omeprazole containing pellets.
CO EP 1010423 A2	Relates to an oral pharmaceutical preparation comprising an antiulcer activity compound, and process for its production.
DA 50 th Edition of Physician's, 1996 Desk Reference p. 529—531.	Relates to omeprazole.

DB September 23, 1994 Decision of the Korean Patent Office Regarding Korean Patent No. 55426 with Certified English Translation See page 4, line 13 to page 5, line 8.	Relates to omeprazole formulation.
DC Korean Patent Application 92-17571 with Certified English Translation	Relates to omeprazole formulation.
DD Declaration of Eugene T. Stevenson, Jr. Chief of Foreign Patents and Scientific Literature Branch at the United States Patent and Trademark Office Scientific and Technical Information Center	Relates to the publication of the abstract for the September 26, 1992 Korean Patent Application, Reference DC above.
DE Korean Open-Laid Patent No. 1016	Relates to the published abstract for the September 26, 1992 Korean Patent Application, Reference DC above.
DF Response to the Appeal Trial Case for the September 24, 1994 Decision (Korean Patent No. 55426) submitted by Chong Hwan Kim with Translator's Certificate	Relates to arguments in an opposition proceeding involving the September 26, 1992 Korean Patent Application, Reference EQ above.
DG Lind et al. "Effect of Omeprazole – A Gastric Proton Pump Inhibitor – On Pentagastrin Stimulated Acid Secretion in Man" Gut, 1983, 24, pgs. 270-276	Relates to effect of omeprazole a gastric proton pump inhibitor on pentagastrin stimulated acid secretion in man.
DH Pilbrant et al. "Development of an Oral Formulation of Omeprazole" Scand J. Gastroenterol 1985; 20 (Suppl 108) pgs. 113-120.	Relates to a development of an oral formulation of omeprazole.

In accordance with current Patent and Trademark Office practice no copy of the above listed United States Patents are filed herewith as well as copies of abstracts in English. Full text copies of all non-United States Patent prior art are enclosed herewith. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

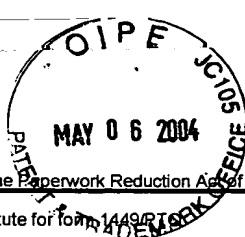
It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made or record therein. It is believed that no fee is required for submission of this Information Disclosure Statement under 37 C.F.R. §1.97(b). However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read 'Martin P. Endres', is written over the typed name and registration number.

Martin P. Endres
Reg. No. 35,498

MAILING ADDRESS:
HEDMAN & COSTIGAN, P.C.
1185 Avenue of the Americas
New York, NY 10036
(212) 302-8989



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for Form 1449, PTO/SB/08A

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1

of 4

Complete if Known

Application Number	10/761,805
Filing Date	January 21, 2004
First Named Inventor	Robert Nicestro
Art Unit	
Examiner Name	
Attorney Docket Number	141-411A

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US- 4,255,431	03-10-1981	Junggren et al.	
	AB	US- 4,359,465	11-16-1982	Ruwart	
	AC	US- 4,686,230	08-11-1987	Rainer et al.	
	AD	US- 4,786,505	11-22-1988	Lovgren et al.	
	AE	US- 4,840,799	06-20-1989	Appelgren et al.	
	AF	US- 4,853,230	08-01-1989	Lovgren et al.	
	AG	US- 5,045,321	09-03-1991	Makino et al.	
	AH	US- 5,178,867	01-12-1993	Guittard et al.	
	AI	US- 5,219,870	06-15-1993	Kim	
	AJ	US- 5,244,670	09-14-1993	Upson et al.	
	AK	US- 5,330,982	07-19-1994	Tyers	
	AL	US- 5,385,739	01-31-1995	Debregeas et al.	
	AM	US- 5,399,700	03-21-1995	Min et al.	
	AN	US- 5,417,980	05-23-1995	Goldman et al.	
	AO	US- 5,433,959	07-18-1995	Makino et al.	
	AP	US- 5,508,041	04-16-1996	Lee et al.	
	AQ	US- 5,693,818	12-02-1997	Von Unge	
	AR	US- 5,714,504	02-03-1998	Lindberg et al.	
	AS	US- 5,753,265	05-19-1998	Bergstrand et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	CA	WO 85/03436	08-15-1985	Kjorn et al.		
	CB	WO 94/02140	02-03-1994	Oishi et al.		
	CC	WO 96/01624	01-25-1996	Bergstrand et al.		
	CD	WO 96/37195	11-28-1996	Scheiwe et al.		
	CE	WO 97/25030	07-17-1997	Lundberg		
	CF	WO 97/25065	07-17-1997	Depui et al.		

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/761,805
Filing Date	January 21, 2004
First Named Inventor	Robert Nicestro
Art Unit	
Examiner Name	
Attorney Docket Number	141-411A

Sheet **2**of **4****U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AT	US- 5,817,338	10-06-1998	Bergstrand et al.	
	AU	US- 5,840,737	11-24-1998	Phillips	
	AV	US- 5,877,192	03-02-1999	Lindberg et al.	
	AW	US- 6,013,281	01-11-2000	Lundberg et al.	
	AX	US- 6,027,746	02-22-2000	Lech	
	AY	US- 6,096,340	08-01-2000	Chen et al.	
	AZ	US- 6,132,770	10-17-2000	Lundberg	
	BA	US- 6,183,776	02-06-2001	Depui et al.	
	BB	US- 6,248,758	06-19-2001	Klokkers et al.	
	BC	US- 6,296,876	10-02-2001	Odidi et al.	
	BD	US- 6,365,184	04-02-2002	Depui et al.	
	BE	US- 6,489,346	12-03-2002	Phillips	
	BF	US- 2002/0192299	12-19-2002	Taneja et al.	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	CG	WO 98/53803	12-03-1998	Erickson et al.		
	CH	WO 00/26185	05-11-2000	Phillips		
	CI	WO 01/03707	01-18-2001	Mandel et al.		
	CJ	WO 02/053097	07-11-2002	Taneja et al.		
	CK	EP 0 124 495	11-07-1984	Brandstrom		
	CL	EP 0 173 664	03-05-1986	Branstrom et al		

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND**
TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO

(Use as many sheets as necessary)

Sheet	3
-------	---

3

Q

4

Complete if Known

Application Number

10/761.805

Filing Date

January 21, 2004

First Named Inventor

Robert Nicestro

Art Unit

Examiner Name

Attorney Docket Number

141-411A

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY			
	CM	EP 0 338 861	01-20-1993	Spickett et al.		
	CN	EP 0 519 144	12-23-1992	Tanberk et al.		
	CO	EP 1010423	06-21-2000	Picornell Darder		

**Examiner
Signature**

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Sheet	4	of	4	Application Number	10/761,805
				Filing Date	January 21, 2004
				First Named Inventor	Robert Nicestro
				Art Unit	
				Examiner Name	
				Attorney Docket Number	141-411A

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	DA	50th Edition of Physician's 1996 Desk Reference p. 529-531.	
	DB	Sept. 23, 1994 Decision of the Korean Patent Office regarding Korean Patent No. 55426 with Certified English Translation. See pg. 4, line 3 to pg. 5, line 8.	
	DC	Korean Patent Application 92-17571 with Certified English Translation.	
	DD	Declaration of Eugene T. Stevenson, Jr. Chief of Foreign Patents and Scientific Literature Branch at the U.S. Patent and Trademark Office Scientific and Technical Information Center.	
	DE	Korean Open-Laid Patent No. 1016.	
	DF	Response to the Appeal Trial Case for the Sept. 24, 1994 Decision (Korean Patent No. 55426) submitted by Chong Hwan Kim with Translator's Certificate.	
	DG	Lind et al. "Effect of Omeprazole - A Gastric Proton Pump Inhibitor - On Pentagastrin Stimulated Acid Secretion in Man" Gut, 1983, 24, pgs. 270-276.	
	DH	Pilbrant et al. "Development of an Oral Formulation of Omeprazole" Scand J. Gastroenterol 1985; 20 (Suppl. 108) pgs. 113-120.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.